


# Webinar Instructions

*Welcome to the Kids First X01 Pre-Application Webinar*

- Every participant is muted upon entry.
- To ask public questions, use the **Q&A** bar (right side of your screen). We encourage you to save these for the question periods.
- You can also use the “chat”  service to send private messages to the host or presenters throughout the webinar.
- After the webinar, additional questions can be emailed to: [valerie.cotton@nih.gov](mailto:valerie.cotton@nih.gov)

***This webinar will be recorded.  
We will start at noon (EDT)***



# Pre-Application Webinar for

## ***PAR-19-390, Discovery of the Genetic Basis of Childhood Cancers and of Structural Birth Defects: Gabriella Miller Kids First Pediatric Research Program (X01 Clinical Trial Not Allowed)***

November 21, 2019

12:00 pm EST



The Common  
Fund



# Agenda

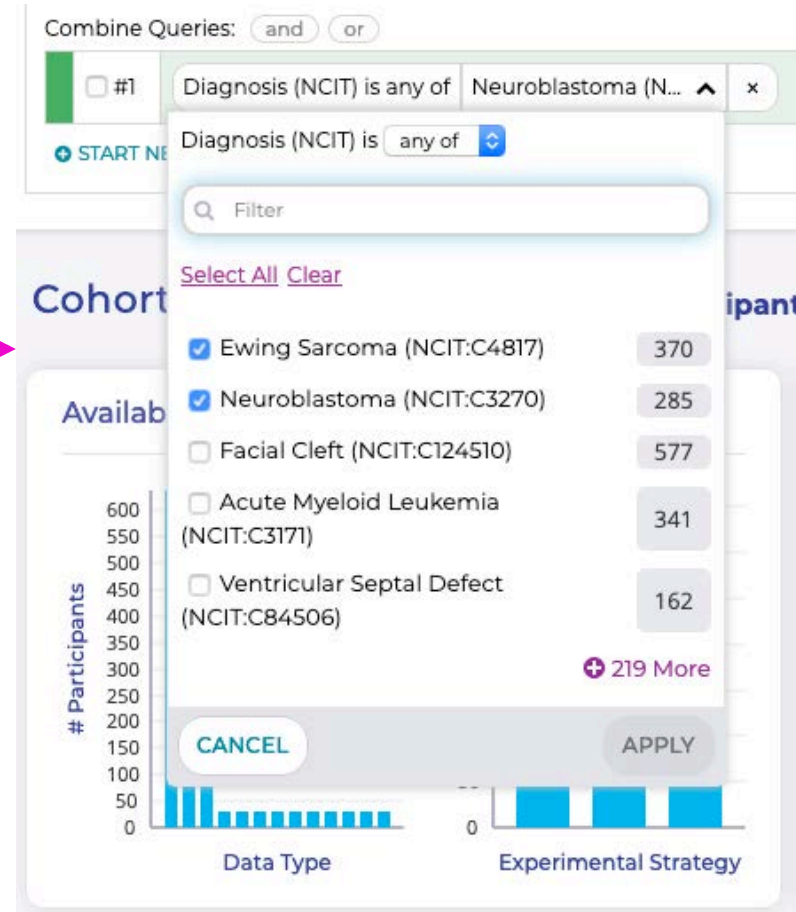
- **12-12:25pm. [PAR-19-390](#) - *Discovery of the Genetic Basis of Childhood Cancers and of Structural Birth Defects: Gabriella Miller Kids First Pediatric Research Program (X01 Clinical Trial Not Allowed)* – Valerie Cotton, NICHD**
- **12:25-12:30pm. [PAR-19-375](#)- *Small Research Grants for Analyses of Gabriella Miller Kids First Pediatric Research Data (R03 Clinical Trial Not Allowed)* – James Coulombe, NICHD**
- **12:30-12:35pm. Common Fund FOA – Marie Nierras**
- **12:35-12:45pm. ORIP FOAs – Sige Zou & Oleg Mirochnitchenko**
- **12:45-12:55pm. NIDCR FOAs – Emir Khatipov**
- **12:55-1pm. Questions & Additional FOAs**



# Watch the Fall Public Webinar from September 26<sup>th</sup>

<https://youtu.be/NDatoQxvLKo>

- Introduction by NIH Kids First staff (~5min)
- New Kids First Data Resource Portal Features – DRC (~30min) →
- Kids First X01 Neuroblastoma Project Findings – Sharon Diskin, PhD (~30min)
- Kids First Program Updates – NIH (~15min)
- Kids First Second Chance – NIH (~10min)
- Questions (~15min)



# Vision

Alleviate suffering from childhood cancer and structural birth defects by fostering **collaborative research** to uncover the etiology of these diseases and supporting **data sharing** within the pediatric research community.



# ***NIH Kids First Working Group***

Kids First is an NIH Common Fund program coordinated by a **trans-NIH Working Group**, which is chaired by four institutes:

*Eunice Kennedy Shriver* National Institute of Child Health and Human Development (**NICHHD**)

National Human Genome Research Institute  
(**NHGRI**)

National Heart, Lung, and Blood Institute  
(**NHLBI**)

National Cancer Institute  
(**NCI**)



The Common  
Fund



Other Working Group Representation:

**NIDCR**

**NIAAA**

**NIDDK**

**NEI**

**NIAID**

**ORIP**

**NIDA**

**NINDS**

**NIEHS**

**NIAMS**

**NCATS**

**CDC**

<https://commonfund.nih.gov/kidsfirst/members>

# Kids First Major Initiatives

\$12.6 million per year for 10 years, pending appropriations

Year | 15 ✓ | 16 ✓ | 17 ✓ | 18 ✓ | 19 ✓ | 20 | 21 | 22 | 23 | 24



## Cohort identification & DNA sequencing

- Identify children with cancer and/or structural birth defects, and their families (X01)
- Whole genome sequencing by the Kids First Sequencing Centers



## Data Resource Center

- Develop a resource of well-curated clinical and genetic sequence data to facilitate and empower genomic discovery
- Provide computational infrastructure and analysis tools to interrogate large and complex datasets



# Kids First X01 Cohorts (Years 1-4)



Disorders of Sex Development (FY15)

Congenital Diaphragmatic Hernia (FY15, 16, 17)

Ewing Sarcoma (FY15, 17)

Orofacial Clefts; Caucasian (FY15), Latin American (FY16), Asian & African (FY17)

Osteosarcoma (FY15)

Structural Heart & Other Defects (FY15, 16, 18)

Syndromic Cranial Dysinnervation Disorders (FY15)

Cancer Susceptibility (FY16)

Adolescent Idiopathic Scoliosis (FY16)

Familial Leukemia (FY16)

Hearing Loss (FY16)

Neuroblastomas (FY16)

Craniofacial Microsomia (FY17)

Enchondromatoses (FY17)

Hemangiomas, Vascular Anomalies & Overgrowth (FY17, 18)

Nonsyndromic Craniosynostosis (FY17)

Patients with both childhood cancer and birth defects (FY17)

Bladder Exstrophy (FY18)

Cornelia de Lange Syndrome (FY18)

Esophageal Atresia and Tracheoesophageal Fistulas (FY18)

Kidney and Urinary Tract Defects (FY18)

Intracranial Germ Cell Tumors (FY18)

Microtia (FY18)

Fetal Alcohol Spectrum Disorders (FY18)

Myeloid Malignancies + overlap with Down syndrome (FY18)

Congenital Heart Defects and Acute Lymphoblastic Leukemia in Children with Down Syndrome (FY18)

- 26 projects
- ~10,000 patients  
(+ family members and tumors)
- 4 X01 cycles
- 8 released datasets





# 2019 X01 Cohorts (Year 5)



Structural Brain Defects

Structural Defects of the Neural Tube (Spina Bifida: Myelomeningocele)

Orofacial Clefts in the Philippines

CHARGE Syndrome

> 10,000 genomes

Laterality Birth Defects

Kidney and Urinary Tract Defects

Esophageal Atresia & Tracheoesophageal Fistulas

Congenital Anomalies of the Kidney & Urinary tract

T-cell Acute Lymphoblastic Leukemia

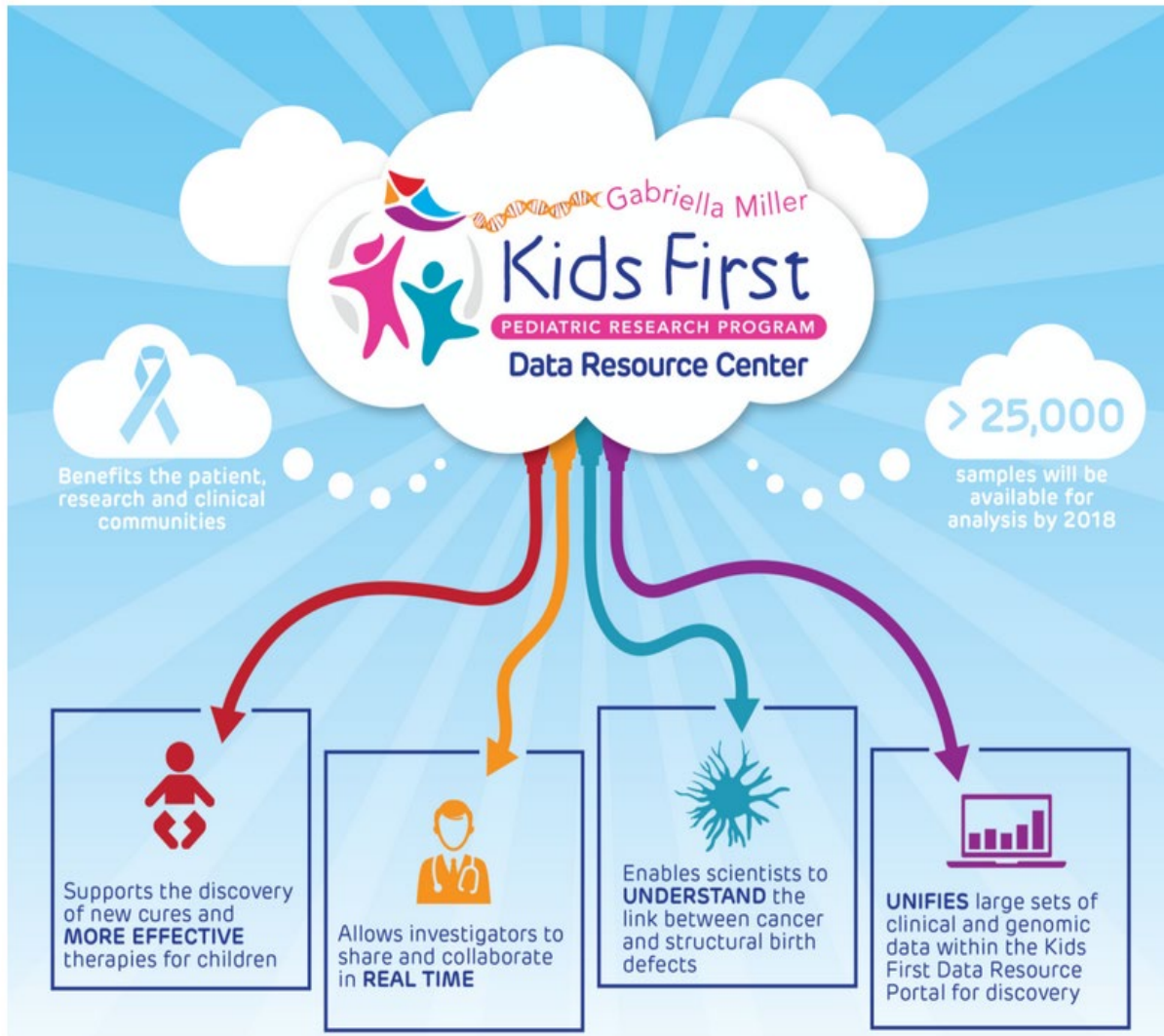
Pediatric Rhabdomyosarcoma

Extracranial Germ Cell Tumors



Abstracts & Contact PIs listed on: <https://commonfund.nih.gov/kidsfirst/x01projects>

# Data Resource Center (DRC)



# Kids First Data Resource Center



## Data Coordination Center

- Clinical & phenotypic data harmonization using ontologies
- Genomic data harmonization against latest reference build with an optimized and scalable pipeline



## Administration & Outreach

- Coordinate and communicate across the DRC
- Engage the broader community including researchers, physicians, patients, and foundation advocates



## Data Resource Portal

- Develop interface to enable users of all skill levels to browse, visualize, and analyze across Kids First and related data
- Develop analytic frameworks and cloud-based workspaces to enable collaborative analysis and empower research



# PAR-19-390 (FY20)

Discovery of the Genetic Basis of Childhood Cancers and of Structural Birth Defects: Gabriella Miller Kids First Pediatric Research Program (X01 Clinical Trial Not Allowed)



# 2020 X01: 6<sup>th</sup> Cycle

*Discovery of the Genetic Basis of Childhood Cancers and of Structural Birth Defects:  
Gabriella Miller Kids First Pediatric Research Program (X01 Clinical Trial Not Allowed)*

1. FY 2015: [PAR-15-259](#)
  - 2 childhood cancer projects
  - 5 structural birth defects projects
2. FY 2016: [PAR-16-150](#)
  - 3 childhood cancer projects
  - 5 structural birth defects projects
3. FY 2017: [PAR-17-063](#)
  - 2 childhood cancer projects
  - 5 structural birth defects projects
  - 1 projects with overlap of structural birth defects and childhood cancer
4. FY 2018: [PAR-18-583](#)
  - 2 childhood cancer projects
  - 7 structural birth defects projects
  - 2 projects with overlap of structural birth defects and childhood cancer
5. FY 2019: [PAR-19-104](#)
  - 3 childhood cancer projects
  - 7 structural birth defects projects
6. FY 2020: [PAR-19-390](#)





# X01 mechanism

- Not an “award”; Recipients are selected for the opportunity to have their cohort sequenced by Kids First sequencing centers and data shared through the Kids First Data Resource
- No Notice of Award; Kids First can provide a letter acknowledging and explaining that your project was selected for the X01 program
- Not listed in the NIH RePORTER
  - Abstracts and X01 information listed on Kids First website: <https://commonfund.nih.gov/kidsfirst/fundedresearch>
- No funds, but can apply for other grants (e.g. Kids First R03) to support analysis of X01 project.



# X01 Selection Considerations

Following **scientific peer review**, Kids First program officers evaluate projects based on the following factors, and selections are finalized by Kids First Working Group Co-Chairs.

- Scientific and technical merit (determined by scientific peer review).
- Value of incorporating the dataset into the Data Resource to empower research among the pediatric research community.
- Balance of childhood cancers and birth defects; conditions not previously sequenced will be prioritized.
- Broad data sharing and use
- Informative study design and sufficient clinical and phenotypic data.
- Availability of samples in timely manner.
- Sample quality in terms of suitability for whole genome sequencing (as well as exome and RNASeq if applicable).





# Data Flow

The Kids First DRC is charged with:

- re-processing and “harmonizing” data generated by the sequencing centers to facilitate analyses across all Kids First datasets
- providing a central portal where these data and analysis tools will be readily accessible to the research community

Phenotypic data →

Sequence data →



**X01 Recipients**

**Pediatric Research  
Community**

*X01 investigators are encouraged to utilize and work collaboratively with the Kids First Data Resource Center to pursue specific analyses. Visit: [kidsfirstdrc.org](https://kidsfirstdrc.org)*

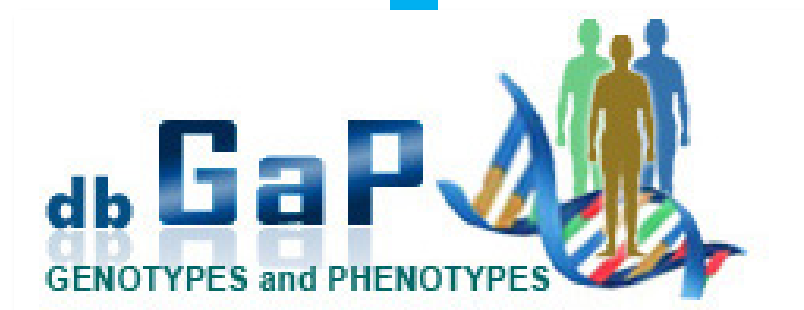
# dbGaP & the DRC

Data is made accessible through dbGaP & Kids First Data Resource Center (DRC)

- While the Data Resource is the NIH designated repository for Kids First data, all Kids First projects are registered, authenticated, and approved through dbGaP
- All dbGaP Data Access Requests (DARs) will be processed by **the Kids First Data Access Committee** run by the NCI Office of Data Sharing



**Kids First  
Data Access Committee  
(NIH)**



# PAR-19-390

## Goals & Expectations

### Overall Goal

Identify a diversity of childhood cancer and structural birth defects cohorts to generate high quality and broadly shareable and usable genomic datasets that will be of high value to the pediatric research community.



# Sequencing



**Goal: Generate high quality whole genome sequence and variant data from childhood cancer and structural birth defects cohorts.**

WGS, whole exome sequencing (WES), and RNA sequencing may be available for tumor or affected tissue, when justified.

## **Expectations:**

- DNA extractions must be of sufficient quality and concentration for WGS (and/or WES).
- RNA extractions (for tumor/affected tissue) must be of sufficient quality and concentration for RNASeq.
- Extractions will be ready to ship shortly after selection

# Sequencing

Sequencing Centers perform sequencing & variant calling  
Generate CRAM/BAM & VCF files

- **Germline/Normal**: WGS at 30X coverage (NovaSeq)
  - **Tumor or Affected tissue** (when available):
    - HudsonAlpha St Jude: 30X WGS + 100X WES + 100X RNASeq
    - Broad: 90X WGS, RNASeq
- *You may propose other approaches (e.g., higher coverage or complementary exome sequencing).*
- *Project design will be finalized in discussions among the X01 investigators, the sequencing centers, and NIH program staff*



# Volume/Concentration Recommendations

Can be found on our FAQ page: <https://commonfund.nih.gov/kidsfirst/FAQ>

Amount of DNA/RNA and coverage

|         | Amount DNA or RNA required/recommended       | Concentration         | Coverage   | Additional info. |
|---------|--|-----------------------|--|------------------|
| WGS     | ~2ug DNA                                     | 20-50 ng/ul preferred | 30X  | paired end reads |
| WES     | 275 ng DNA (minimum); 1 ug recommended       | 20 ng/ul (minimum)    | 100X, greater than 80% coding exons covered at 20X | paired end reads |
| RNA-Seq | 750 ng total RNA (minimum); 1 ug recommended | 20 ng/ul (minimum)    | 100X, greater than 40% coding exons covered at 20X | paired end reads |



# Data Sharing



## Goals:

- 1. Make data generated by Kids First as accessible and usable as possible to the research community.**
- 2. Enable researchers to easily combine/compare datasets for cross-disease analyses.**

## Expectations:

- Individual-level sequence and relevant phenotypic data are approved for deposition in a NIH-approved repository (e.g. dbGaP)
- Samples that are consented in a way that allows broad access and use, including combining and cross-analyzing datasets (General Research Use, Health/Medical/Biomedical), will be prioritized

*See below and visit [Kids First Genomic Data Sharing FAQs](#) for more information*



# X01 Data Access & Six Month Pre-Release Period

- X01 investigators have six (6) months of proprietary access to the dataset before it is made available to the public.
- Pre-release period starts when the X01 team has access to all individual level sequence data (BAM/CRAM, VCFs)

Access Sequence  
Data!

Pre-release Analyses

Public Release



0-6 months

6+ months

X01 PIs & Collaborators  
(including Kids First Sequencing Centers & DRC)

Pediatric Research Community  
(request access via dbGaP)





# Analysis Plans

**Goal:** Have investigators demonstrate that the proposed project has an adequate research design for genetic discovery, and that the X01 applicants are prepared to perform these analyses

**Expectations:**

- While Kids First recognizes that analytical power will increase when the data from each individual study is incorporated with other data that will be part of the Data Resource, it is important to demonstrate that the data will be useable on its own
- Consider partnering with other research teams with relevant expertise to develop the analysis plan



# Study Design

**Goal:** Study design, sample size, and family structures are sufficient to lead to genetic discovery

**Expectations:**

- Large sample sizes preferred
  - Consider collaborating with other investigators to pool samples together
- Non-trio family designs: describe the number of probands and affected/unaffected family members proposed for sequencing

# Clinical/Phenotypic Data



**Goal: Well-phenotyped data empowers analyses and informs how pathways/conditions overlap.**

The DRC will leverage existing community standards to harmonize clinical/phenotypic data which facilitates searching, analysis, and interoperability with other data efforts.

## **Expectations:**

- Basic data elements are expected and deep phenotyping is preferred.
- Describe what clinical/phenotypic information is available and how these data will:
  - 1) support your proposed analysis
  - 2) contribute to the DRC to empower collaborative research



# Program Balance

**Goal**: Broaden the diversity of both childhood cancer and structural birth defects datasets that are represented in the Data Resource

**Expectation**: Priority may be given to cohorts representing conditions not previously sequenced by Kids First (if many applications score well and meet other criteria)

# Other Attachments

1) Institutional Certification (or provisional certification with data use limitations designations)

2) Sample Information

3) Clinical/Phenotypic Data

4) Family Structure (Optional)

fillable tables  
(optional)



# Institutional Certification: Steps

- 1) Download the current NIH Institutional (or Provisional) Certification template:  
<https://osp.od.nih.gov/scientific-sharing/institutional-certifications/>  
**\*template was updated on November 1, 2018\***
- 2) Fill out the first page, include all sites contributing samples for sequencing.
- 3) Provide the Institutional Certification to the IRB along with the participant consent forms for each site and any other pertinent information.
- 4) The IRB reviews the consent form(s) to determine the data use limitations (DULs) and/or DUL modifiers for each consent form.
  - **“General Research Use” with no modifiers is expected for individual-level data, unless specific uses are clearly prohibited in the participant consent**
  - **“Unrestricted” access is expected for genomic summary results unless the IRB provides a justification for designating the dataset as “sensitive”**
- 5) After IRB review, the Institutional Certification is signed by the appropriate officials and submitted to NIH.



[Download](#) a letter that explains these steps



# Institutional Certification: Page 1

Date: [MM/DD/YYYY] 12/03/2018  
Name of GPA: Jaime Guidry Auvil  
Genomic Program Administrator  
NCI, NIH, HHS  
9000 Rockville Pike  
Bethesda, MD 20892-7395

GPA: Jaime Guidry Auvil, NCI

Re: Institutional Certification of [NAME OF INSTITUTION] to Accompany  
Submission of the Dataset from [ORIGINAL STUDY NAME<sup>1</sup>] for  
[PROJECT TITLE FOR DATA TO BE SUBMITTED]  
to an NIH-designated data repository.

Dear Jaime Guidry Auvil,

The submission of data to the NIH-designated data repository is being made with institutional approval from  
\_\_\_\_\_, along with appropriate institutional approvals from  
collaborating sites, as listed here:

[IF APPLICABLE ENTER COLLABORATING SITE NAMES HERE AND CLICK 'ADD TO LIST']

| LIST OF COLLABORATING SITES                         |   |
|---|---|
| <input type="text"/>                                | <input type="text"/>                      |
| <input type="button" value="Add to list &gt;&gt;"/> | <input type="button" value="Clear list"/> |

The \_\_\_\_\_ hereby assures that submission of data from the study entitled  
\_\_\_\_\_ to an NIH-designated data repository meets  
the following expectations, as defined in the [NIH Genomic Data Sharing Policy](#):

List all sites contributing samples

- The data submission is consistent, as appropriate, with applicable national, tribal, and state laws and regulations as well as relevant institutional policies.
- Any limitations on the research use of the data, as expressed in the informed consent documents, are delineated in the table on page 3.
- The identities of research participants will not be disclosed to NIH-designated data repositories.
- An Institutional Review Board (IRB), and/or Privacy Board, and/or equivalent body, as applicable, has reviewed the investigator's proposal for data submission and assures that:
  - The protocol for the collection of genomic and phenotypic data is consistent with [45 CFR Part 46](#).<sup>2</sup>
  - Data submission and subsequent data sharing for research purposes are consistent with the informed consent of study participants from whom the data were obtained;
  - Consideration was given to risks to individual participants and their families associated with data submitted to NIH-designated data repositories and subsequent sharing, including unrestricted access to genomic summary results;
  - To the extent relevant and possible, consideration was given to risks to groups or populations associated with submitting data to NIH-designated data repositories and subsequent sharing, including unrestricted access to genomic summary results; and
  - The investigator's plan for de-identifying datasets is consistent with the standards outlined in the [NIH Genomic Data Sharing Policy](#) (See section IV.C.1).

<sup>1</sup> Certification must be provided for all sites contributing samples. If more than one site is contributing samples, the primary site may submit one Institutional Certification indicating that they are providing certification on behalf of all collaborating sites. Alternatively, each site providing samples may provide its own Institutional Certification.

# Institutional Certification: Page 2

The individual-level data are to be made available through (check one)

- ☒ controlled-access <sup>3</sup>
- ☐ unrestricted access <sup>4</sup>

individual-level sequence data are expected to be “controlled-access”, unless consent allows for unrestricted access

If **unrestricted access** is marked, the data use limitations table on the following page(s) does not need to be completed.

NIH provides genomic summary results<sup>5</sup> (GSR) from most studies submitted to NIH-designated data repositories through unrestricted access. However, data from data sets considered to have particular ‘sensitivities’ related to individual privacy or potential for group harm (e.g., those with populations from isolated geographic regions, or with rare or potentially stigmatizing traits) may be designated as “sensitive” by

In such cases, “controlled-access” should be checked below and a brief explanation for the sensitive designation should be provided. GSR from any such data sets will only be available through controlled-access.

The genomic summary results (GSR) from this study are only to be made available through ☐ controlled-access.

Explanation if controlled-access was selected for GSR.

Keep unchecked for “unrestricted” access to genomic summary results unless the IRB provides a justification for designating the dataset as “sensitive”



# Institutional Certification: Page 3

NIH expects the submitting institution(s) to select one of the three standard [Data Use Limitations](#) (DULs) for appropriate secondary use, or, if necessary, create a customized DUL. **DULs are developed based on the original informed consent of the participant(s).**

## Data Use Limitations

|                                 |     |  |
|---------------------------------|-----|--|
| General Research Use            | GRU | Use of the data is limited only by the terms of the Data Use Certification: these data will be added to the <a href="#">dbGaP Collection</a> . |
| Health/Medical/Biomedical       | HMB | Use of the data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.                |
| Disease-specific [list disease] | DS  | Use of the data must be related to the specified disease.  |
| Other                           |     | [ENTER CUSTOMIZED TEXT, IF APPLICABLE]   |

Additional modifiers to the standard DULs (e.g., Not-for-profit Use Only) basis in the informed consent from the participants or in special knowledge.

## Data Use Limitation Modifiers (Optional)

|                         |     |  |
|-------------------------|-----|--|
| IRB Approval Required   | IRB | Requestor must provide documentation of local IRB approval.  |
| Publication Required    | PUB | Requestor agrees to make results of studies using the data available to the larger scientific community.         |
| Collaboration Required  | COL | Requestor must provide a letter of collaboration with the primary study investigator(s).                         |
| Not-for-profit Use Only | NPU | Use of the data is limited to not-for-profit organizations.  |
| Methods                 | MDS | Use of the data includes methods development research (e.g., development and testing of software or algorithms). |
| Genetic Studies Only    | GSO | Use of the data is limited to genetic studies only.  |

**“General Research Use” with no modifiers is expected for individual-level data, unless specific uses are clearly prohibited**

Using the tables above, please indicate in the table below the consent group(s) for each collaborating study site. Use one row per consent group.

| Collaborating Site Name | Data Use Limitation                       | Data Use Limitation Modifiers (optional)   |
|-------------------------|---|--|
| Eg: Cold Cohort Study   | Health/Medical/Biomedical                 | IRB <input type="checkbox"/> PUB <input type="checkbox"/> COL <input type="checkbox"/> NPU <input type="checkbox"/> MDS <input type="checkbox"/> GSO <input type="checkbox"/>            |
| Eg: Cold Cohort Study   | Disease Specific Research [ Lung Cancer ] | IRB <input type="checkbox"/> PUB <input type="checkbox"/> COL <input type="checkbox"/> NPU <input checked="" type="checkbox"/> MDS <input type="checkbox"/> GSO <input type="checkbox"/> |
| <input type="text"/>    | General Research Use                      | IRB <input type="checkbox"/> PUB <input type="checkbox"/> COL <input type="checkbox"/> NPU <input type="checkbox"/> MDS <input type="checkbox"/> GSO <input type="checkbox"/>            |
| <input type="text"/>    | Select consent group title                | IRB <input type="checkbox"/> PUB <input type="checkbox"/> COL <input type="checkbox"/> NPU <input type="checkbox"/> MDS <input type="checkbox"/> GSO <input type="checkbox"/>            |
| <input type="text"/>    | Select consent group title                | IRB <input type="checkbox"/> PUB <input type="checkbox"/> COL <input type="checkbox"/> NPU <input type="checkbox"/> MDS <input type="checkbox"/> GSO <input type="checkbox"/>            |

*The following data use limitations and modifiers limit broad data access and impede the ability of the Kids First program to accomplish its goals*

- **Disease Specific Consent Group:** When data use is restricted to a specific disease area, the data cannot be combined with a dataset with a different disease specific data use limitation. Combining and cross-analyzing datasets are a primary goal of Kids First and therefore datasets that are consented for General Research Use and/or Health/Medical/Biomedical purposes will be prioritized over datasets restricted to Disease Specific use.
- **IRB modifier:** With this box checked, the Requester must provide documentation of a their local IRB's approval for the proposed research. We find that it is rare for consent language to include such a requirement and that this modifier is often included in error. As a reminder, every requester and their institution must agree to the terms of the Data Use Certification (DUC), which verifies that the requesting PI is accredited within the institution, the institution is aware of the project for which the PI is proposing to use the data, and that the Institution has all appropriate security measures in place to manage and maintain the controlled-access dataset(s) being retrieved. For a sample DUC, see: [https://osp.od.nih.gov/wp-content/uploads/Model\\_DUC.pdf](https://osp.od.nih.gov/wp-content/uploads/Model_DUC.pdf)
- **COL modifier:** This box is checked when the consent form states that collaboration with the original/submitting investigator is required in order to use the dataset; therefore, the Requestor must provide a collaboration agreement document in order to be approved for access the dataset. This can limit the number of end-users who are able to use the dataset.

*For more detail on DUL definitions:*

[https://osp.od.nih.gov/wp-content/uploads/NIH\\_PTC\\_in\\_Developing\\_DUL\\_Statements.pdf](https://osp.od.nih.gov/wp-content/uploads/NIH_PTC_in_Developing_DUL_Statements.pdf)

# Genomic Data Sharing Contacts

**Jaime M. Guidry Auvil, Ph.D.**

**Genomic Program Administrator (GPA)**

Director, NCI Office of Data Sharing

[NCIOfficeofDataSharing@mail.nih.gov](mailto:NCIOfficeofDataSharing@mail.nih.gov)

**Vivian Ota Wang, Ph.D.**

**Kids First Data Access Committee (DAC) Chair**

Deputy Director, NCI Office of Data Sharing

[KidsFirstDAC@nih.gov](mailto:KidsFirstDAC@nih.gov)

General NIH Genomic Data Sharing questions: [GDS@mail.nih.gov](mailto:GDS@mail.nih.gov)



# Other Attachments

1) Institutional Certification (or provisional certification with description of data use limitations)

2) Sample Information

3) Clinical/Phenotypic Data

4) Family Structure (Optional)

**fillable tables**  
(optional)



<https://commonfund.nih.gov/kidsfirst/FAQ>

# Other Attachments: Fillable Table

## Provisional Certification

### 1) **Provisional Certification: Data Sharing and Data Use Limitations**

If you provided a Provisional Institutional Certification, because you are unable to provide a full Institutional Certification, please describe the anticipated data use limitations based on the language of the consent form(s) signed by the participants in the proposed cohort. For a list of standard DULs and modifiers, please review the Institutional Certification template: <https://osp.od.nih.gov/scientific-sharing/institutional-certifications> or [https://osp.od.nih.gov/wp-content/uploads/standard\\_data\\_use\\_limitations.pdf](https://osp.od.nih.gov/wp-content/uploads/standard_data_use_limitations.pdf).

| <u>Site</u> | <u>Data Use Limitation (GRU, HMB, DS)</u> | <u>Data Use Limitation Modifiers (IRB, PUB, COL, NPU, MDS, GSO)</u> |
|-------------|---|---|
|             |   |   |
|             |   |   |
|             |   |   |
|             |   |   |
|             |   |   |





# Other Attachments: Fillable Table

## Sample Information

| <u>DNA (and RNA) tissue of origin</u>  | <u>Number of Samples</u> | <u>Extraction Method</u> | <u>Concentration</u> | <u>Quality</u><br>(Metric used: <i>[edit here to specify]</i> ) | <u>Method of Quantitation</u> | <u>Number of Samples Ready to Ship by August 2019</u> | <u>Number of Samples Ready to Ship by January 2020</u> |
|--|--------------------------|--------------------------|----------------------|---|-------------------------------|---|--|
| Blood  |                          |                          |                      |   |                               |   |  |
| Saliva or Buccal swab  |                          |                          |                      |   |                               |   |  |
| [other tissue, edit here to describe].<br><b>Note: cell lines will not be accepted</b> |                          |                          |                      |   |                               |   |  |
| Tumors or Affected Somatic Tissue  |                          |                          |                      |   |                               |   |  |
| DNA – Frozen Tissue  |                          |                          |                      |   |                               |   |  |
| RNA – Frozen Tissue  |                          |                          |                      |   |                               |   |  |
| DNA – Embedded Tissue  |                          |                          |                      |   |                               |   |  |
| RNA – Embedded Tissue  |                          |                          |                      |   |                               |   |  |
| <b>Total</b>   |                          |                          |                      |   |                               |   |  |

\*For tumor specimens or affected tissue samples, please also describe the fixation methods and the pathology review to which the specimens were subjected, separate from the table. For tumors, describe the percentage of tumor cells within the specimen used for DNA and/or RNA isolation and % necrosis.

# Other Attachments: Fillable Table

## Clinical/Phenotypic Data & Demographics

**Available Phenotype or Clinical Information (for #3 Clinical, Phenotypic, and Demographic Data).** Please edit or add to the table below to indicate what phenotype information is available for the case/proband, parents, and/or other family members. The information you list is intended to be shared through the Kids First Data Resource.

| <b>Demographics</b>   | Case/Proband/Affected | Unaffected family members/parents |
|---|-----------------------|-----------------------------------|
| <input type="checkbox"/> Age at enrollment or age at diagnosis                                    |                       |                                   |
| <input type="checkbox"/> Other age information (age at specimen collection, age at death etc....) |                       |                                   |
| <input type="checkbox"/> Sex  |                       |                                   |
| <input type="checkbox"/> Race   |                       |                                   |
| <input type="checkbox"/> Hispanic ethnicity   |                       |                                   |
| <input type="checkbox"/> List any other demographic information:                                  |                       |                                   |

| <b>Clinical information (e.g., diagnoses, type of birth defect, primary tumor type, vital status, age at last know vital status, treatment information).</b> |                       |                                   |
|--|-----------------------|-----------------------------------|
|  | Case/Proband/Affected | Unaffected family members/parents |
| List the variables:  |                       |                                   |
| Are electronic health records available?   |                       |                                   |

| <b>Other phenotypic information (e.g., other phenotypic measurements that may be related to the primary outcome)</b> |                       |                                   |
|--|-----------------------|-----------------------------------|
|  | Case/Proband/Affected | Unaffected family members/parents |
| List the variables   |                       |                                   |

| <b>Family medical history (e.g., family history of birth defects, family history of cancer)</b> |                       |                                   |
|---|-----------------------|-----------------------------------|
|   | Case/Proband/Affected | Unaffected family members/parents |
| List the variables:   |                       |                                   |

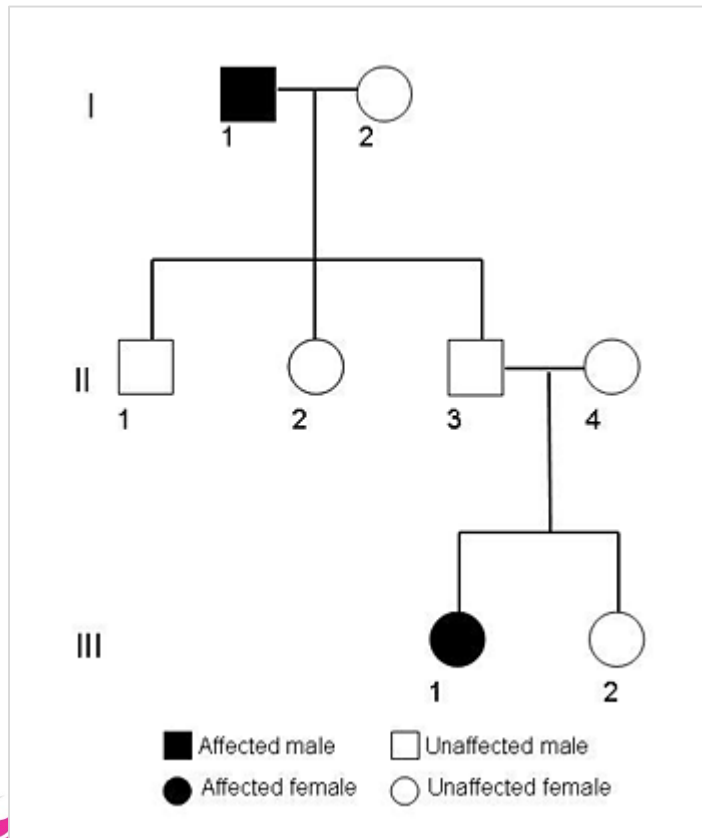
# Biospecimen & Phenotypic Data Elements

|   |  |  |             |  |                     |  |   |                            |                                 |   |
|---|--|--|-------------|--|---------------------|--|---|----------------------------|---------------------------------|---|
| kf_Clinical Elements List - 2018 X01 - Excel  |  |  |             |  |                     |  |   |                            |                                 |   |
| File Home Insert Draw Page Layout Formulas Data Review View Help Acrobat Tell me what you want to do  |  |  |             |  |                     |  |   |                            |                                 |   |
| B3 : X ✓ fx Biomaterial aliquot ID sent to the sequencing center. Some participants or samples may have multiple aliquots and as such should have a separate entry per aliquot sent to the sequencing center. The A |  |  |             |  |                     |  |   |                            |                                 |   |
|   | A  | B  | C           | D  | E                   | F  | G   | H                          | I                               | J   |
|   | Kids First Phenotype/Clinical Minimum Data Fields Descriptors Nov 2018 | Please do not use this sheet to submit data to the KF DRC (a separate template will be provided at a later point in time). See second tab for standard terminology to use if fields are missing, unknown, etc.   |             |  |                     | Examples                                   |   |                            |                                 |   |
| 1   |  |  |             |  |                     |  |   |                            |                                 |   |
| 2   | Field  | Description  | Cohort type | Requirements   | Data Type           |  |   |                            |                                 |   |
| 3   | Aliquot ID   | Biomaterial aliquot ID sent to the sequencing center. Some participants or samples may have multiple aliquots and as such should have a separate entry per aliquot sent to the sequencing center. The Aliquot ID could be identical to a Participant ID in the case where there is only one aliquot per individual being sent to the sequencing center | All         | Required   | Free text           | A215735-01a                                | 1249521A_1  | 147192-b                   | 729-125-P1                      | 800-555_1   |
| 4   | Sample ID  | If multiple aliquots have been sent from the same sample (e.g. for WGS and RNA-Seq characterization) a sample ID that links them together.   | All         | Optional   | Free Text           | S003-125                                   | 124952  | 147                        | 729-125                         | 597   |
| 5   | Participant ID   | Deidentified unique ID for a participant.  | All         | Required   | Free text           | A215735-01                                 | 1249521A  | P002                       | 729-125-P1                      | 800-555   |
| 6   | Family ID  | Family Group ID  | All         | Required   | Free text           | 157  | 1249521   | 217FAM                     | 729-125                         | F800-555  |
| 7   | Consent Group  | Indicate which data use limitation, as indicated on the provided Institutional Certification, is associated with each participant  | All         | Required   | Selection           | General Research Use (GRU)                 | General Research Use with not-for-profit Use only (GRU-NPU) | General Research Use (GRU) | Health/Medical/ Biomedica (HMB) | Health/Medical/ Biomedical with not-for-profit use only (HMB-NPU)       |
| 8   | Affected Status  | If the participant is considered affected as part of the study   | All         | Required   | Selection           | TRUE                                       | TRUE  | FALSE                      | Not Applicable                  | Not Applicable  |
| 9   | Sample Composition   | Saliva, Blood, Solid Tissue, Derived Cell Lines  | All         | Required   | Selection           | Blood                                      | Blood   | Saliva                     | Solid Tissue                    | Buccal Cells  |
| 10  | Sample Anatomical Location   | If blood, draw location is known or other method of blood acquisition. In the case of tissue biopsy samples, note the location of the biopsy. If possible, please use the Uberon ontology.   | All         | Optional   | Selection           | Not Available                              | Not Available   | Mouth                      | R adrenal gland                 | Cheek and Mouth   |
| 11  | Sample Method of Procurement   | biopsy, tumor resection, autopsy, blood draw   | All         | Optional   | Selection           | Blood Draw                                 | Blood Draw  | Saliva Kit                 | Needle Biopsy                   | Cheek Swab  |
| 12  | Family Relationship  | Proband, Mother, Father, Sister, Brother (consult spreadsheet Family Codes for more)   | All         | Required   | Selection           | Proband                                    | Proband   | Father                     | Proband                         | Proband   |
| 13  | Sex  | Female, Male, Other (please specify)   | All         | Required   | Selection           | Female                                     | Female  | Male                       | Male                            | Female  |
| 14  | Race   | White, American Indian or Alaska Native, Black or African American, Asian, Native Hawaiian or Other Pacific Islander, Other  | All         | Required   | Selection           | White                                      | American Indian or Alaska Native                            | White                      | Not allowed to collect          | Not allowed to collect  |
| 15  | Ethnicity  | Hispanic or Latino, Not Hispanic or Latino   | All         | Required   | Selection           | Hispanic or Latino                         | Not Hispanic or Latino                                      | Not Hispanic or Latino     | Not allowed to collect          | Not allowed to collect  |
| 16  | Enrollment Age Days  | Number of days from birth to study enrollment  | All         | One of enrollment age or diagnosis age required for probands     | Free text           | Not Reported                               | Not Reported  | 10220                      | 1825                            | 4380  |
| 17  | Phenotypes Text  | Free text, phenotypes known to exist for the participant in the study, separated by semicolons. In parental rows, can include parental phenotypes  | All         | Either study phenotypes or study diagnoses required for probands | Free text           | Craniosynostosis; Auricular Pit; Club Foot | Congenital Diaphragmatic Hernia; Tetralogy of Fallot        | Short Stature < 2 SD       | Not Reported                    | Post-treatment hypothyroidism; post-treatment growth hormone deficiency |
| 18  | Phenotypes HPO   | HPO terms separated by commas or semicolons of the known phenotypes for the participant in the study   | All         | Encouraged   | Ontology, free text | HP:0030025, HP:0001762, HP:0001363         | HP:0001636, HP:0000776                                      | HP:0004322                 | Not Reported                    |   |
|   |  |  |             | One of   |                     |  |   |                            |                                 |   |

# Other Attachments: Pedigree or Table

Describe Family structures (proband-parent dyads, proband-parent-sibling quads, multiplex families, consanguineous families)

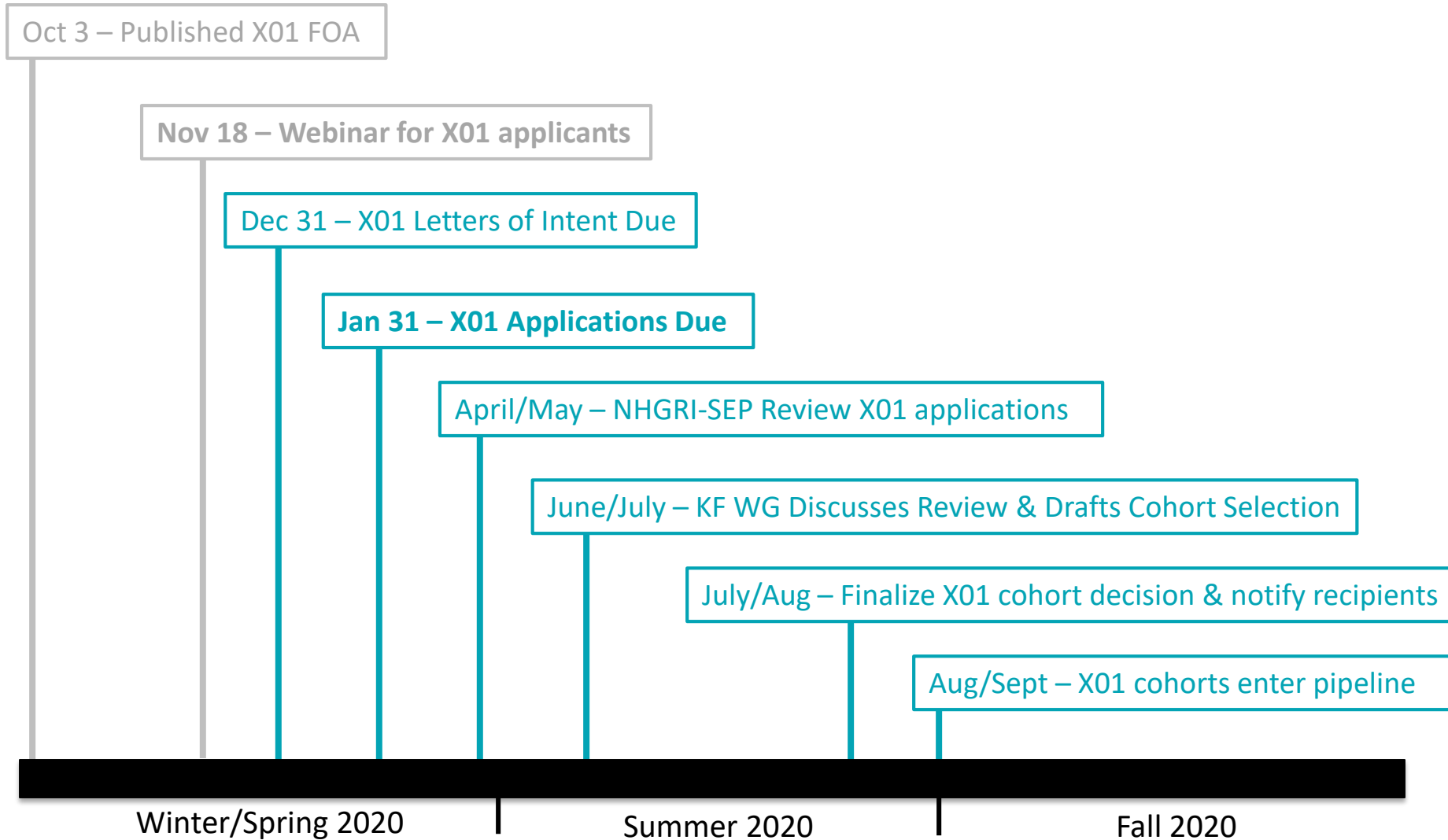
- How many samples per family? How many are affected/unaffected?



| <u>Family type</u>                              | <u>Number of families</u> | <u>Total Germline Samples</u> |
|---|---------------------------|-------------------------------|
| Proband/Child + Parents<br>(unaffected) Trios   | XX                        | XX affected<br>XX unaffected  |
| Proband + 1 affected FDR +<br>[Unaffected FDRs] | XX                        | XX affected<br>XX unaffected  |
| Proband + 2 affected FDR +<br>[Unaffected FDRs] | XX                        | XX affected<br>XX unaffected  |
| <b>Total</b>                                    | <b>XXX</b>                | <b>XXX</b>                    |

FDR= First Degree Relative

# 2020 X01 Timeline





# Agenda

- **12-12:25pm. PAR-19-390 - *Discovery of the Genetic Basis of Childhood Cancers and of Structural Birth Defects: Gabriella Miller Kids First Pediatric Research Program (X01 Clinical Trial Not Allowed)* – Valerie Cotton, NICHD**
- **12:25-12:30pm. PAR-19-375- *Small Research Grants for Analyses of Gabriella Miller Kids First Pediatric Research Data (R03 Clinical Trial Not Allowed)* – James Coulombe, NICHD**
- **12:30-12:35pm. Common Fund FOA – Marie Nierras**
- **12:35-12:45pm. ORIP FOAs – Sige Zou & Oleg Mirochnitchenko**
- **12:45-12:55pm. NIDCR FOAs – Emir Khatipov**
- **12:55-1pm. Questions & Additional FOAs**



# *Small Research Grants for Analyses of Gabriella Miller Kids First Pediatric Research Data*

*(R03 - Clinical Trial Not Allowed)*

**PAR-19-375**



**Purpose:** support analyses of Kids First X01 datasets and appropriate tools development

- NICHD, NCI, NHLBI, NIAAA, and NIDCR
- Standard Receipt Dates (after Open Date): Feb 2020
- Combined direct cost budget for the two-year project period may not exceed \$200,000
- Contact IC representative or James Coulombe  
([coulombej@mail.nih.gov](mailto:coulombej@mail.nih.gov))



# *Small Research Grants for Analyses of Gabriella Miller Kids First Pediatric Research Data*

*(R03 - Clinical Trial Not Allowed)*

**PAR-19-375**



## **FOA Updates**

- Data and Resource Sharing Plans:
  - “data..., tools, workflows, and/or pipelines ***created*** or ***used*** ...will be provided to the Kids First Data Resource Center to be shared with the wider scientific community... in ***a timely manner*** that would enable other researchers to replicate and build on the analyses for future research efforts.”
  - For applications that aim to co-analyze Kids First X01 data with non-Kids First genomic datasets, describe:
    - the database through which the non-KF data are accessible, or
    - ability & willingness to submit the non-KF sequence data to an NIH-approved repository (e.g., dbGaP)





# ***Small Research Grants for Analyses of Gabriella Miller Kids First Pediatric Research Data***

*(R03 - Clinical Trial Not Allowed)*

**PAR-19-375**



- Are “junior” investigators eligible? **Yes!**
- If your institution is willing to submit your application, you are eligible.
- For R03s there are no special considerations for New or Early Stage Investigators.
- However, R03s are a great mechanism for producing preliminary data that can lead to other applications.



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# *Pilot Projects Enhancing Utility and Usage of Common Fund Data Sets*

*(R03 Clinical Trial Not Allowed)*



**RFA-RM-19-012**

- **Purpose**: Small research (R03) grants provide flexibility for initiating discrete, well-defined projects that can be completed in one year, for up to \$200,000 in direct costs
- Examples of research that will be supported:
  - Conducting pilot or feasibility studies based on analyses across Common Fund datasets;
  - Building synthetic cohorts, combining and comparing datasets;
  - Developing research methods, or analytic tools to support data visualization, harmonization and integration;
  - Curating and or annotating genomic information in the datasets;
  - Collecting additional phenotypic or clinical data to enhance datasets.
- Contact KF, or Ananda Roy ([ananda.roy@nih.gov](mailto:ananda.roy@nih.gov))

# Agenda

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OFFICE OF RESEARCH  
INFRASTRUCTURE PROGRAMS

Division of Comparative Medicine

A photograph of a laboratory setting. In the foreground, a black mouse is perched on the back of a person wearing a white lab coat. The background is slightly blurred, showing laboratory equipment like racks of blue and green pipette tips and various glassware.

## ***ORIP Resource-Related Programs***

***Sige Zou, PhD and Oleg Mirochnitchenko, PhD***

***Division of Comparative Medicine***

***Office of Research Infrastructure Programs***

***Division of Program Coordination, Planning, and Strategic Initiatives***

***Office of the Director***



National Institutes of Health  
Office of Research Infrastructure Programs



# Office of Research Infrastructure Programs

## Mission:

*Infrastructure and Resources for Innovation*

## Division of Comparative Medicine

- Centers and research resources
- Research project grants
- Training and career development programs for veterinarian-scientists

## Division of Construction & Instruments

- Construction awards
- Shared instrumentation grant and high-end instrumentation programs (S10)

## SBIR/STTR Programs



<https://orip.nih.gov/>

# Division of Comparative Medicine

- **ORIP's Strategic Plan:**
  - Development and enhancement of models of human disease as well as expansion and accessibility of these models
  - Provide better models of human disease conditions of interest to multiple NIH ICs
- **Major Types of Activities to Support Animal Models of Disease**
  - Center Grants (e.g. P51, P40, and U42)
  - Resource-Related Research Project Grants (e.g. R24)
  - Research Project Grants (e.g. R21)
- **Requirements of Grant Applications:**
  - Demonstrate a need for a resource by the broad research community
  - Applicable to the interests of multiple NIH ICs



# Research Project Grants (R21)

## Funding Opportunity Title (PAR-19-369):

- Development of Animal Models and Related Biological Materials for Research (R21 Clinical Trial Not Allowed)

## Purpose:

- Encourages innovative research to develop, characterize, and improve animal models, biological materials, and technologies

## General Characteristics:

- Support conceptual stages of project development
- No preliminary data required
- Cannot be renewed

## Topics of Interest for ORIP:

- Development or characterization of animal models
- Development of novel technologies for improving animal models
- Complementary approaches to the use of animals, such as animal-tissue-on-chip models
- Informatics and artificial intelligence tools for deep phenotyping





# Resource-Related Research Projects Grants (R24)

## Funding Opportunity Title (RFA-OD-19-027):

- Resource-Related Research Projects for Development of Animal Models and Related Materials (R24 Clinical Trials Not-Allowed)

## Purpose:

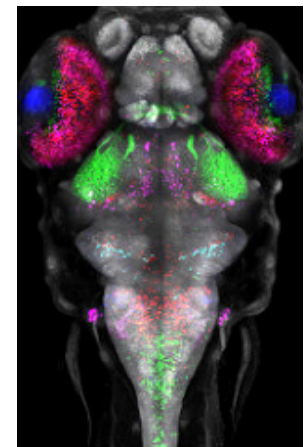
- Develop, characterize, or improve animal models
- Improve diagnosis and control of disease of laboratory animal

## General Characteristics:

- Used to provide a substantial amount of resources to research projects or to enhance research infrastructure
- Cost recovery is not required

## Topics of Interest for ORIP:

- Mutant or transgenic animal models
- Antibodies, genetic resources or other reagents
- Information resources, such as cellular phenotypes
- Animal resources for supporting trans-NIH initiatives



# Animal & Biological Material Resource Centers (P40)

## Funding Opportunity Title (PAR-17-006):

- Animal and Biological Material Resource Centers (P40)

## Purpose:

- Provide support for special colonies of laboratory animals and animal-related models, as well as other resources such as informatics tools, reagents, cultures (cells, tissues, and organs) and genetic stocks that serve the biomedical research community in a variety of research areas on a local, regional, national and international basis.





# Animal & Biological Material Resource Centers (P40)

## General Characteristics:

- As part of ORIP's trans-NIH emphasis, Animal and Biological Material Resource Centers to be developed must address the research interests of multiple NIH Institutes and Centers
- Applications must demonstrate a wide community need for the proposed Resource Centers
- Animal and Biological Material Resource Centers must be available and utilized by investigators on a local, regional, and national basis
- These Resource Centers should ensure the quality and welfare of distributed animals and supply expertise to guide reliable studies
- Institution submitting the application must be committed to the Resource Center being proposed
- Growth of the Resource Centers should result from Program Income
- Applications must include a marketing plan, community outreach strategies and approaches for tracking metrics
- Resource Centers are expected to register their catalogs with current resource tagging and identification initiatives such as FORCE 11

# Current Resource Centers Portfolio


## Biological Materials and Informatics, Other

- 
- 
- National Natural Toxins Research Center
  - Referral Center for Animal Models of Human Genetic Disease
  - Nonhuman Primate Reagent Resource
  - *Drosophila* Genomics Resource Center
  - Center for Neuroanatomy with Neurotropic Viruses
  - *Caenorhabditis* Genetics Center

## Primate

- 
- Squirrel Monkey Breeding and Research Resource
  - Vervet Research Colony
  - Specific Pathogen Free Baboon Research Resource
  - Caribbean Primate Research Center

## Rodent

- 
- National Gnotobiotic Rodent Resource
  - Rat Resource and Research Center
  - Special Mouse Strains Resource
  - Resource for Rat Genetic Models of Aerobic Capacity

## Amphibian

- 
- National *Xenopus* Resource Center
  - *Ambystoma* Genetic Stock Center

## Fish

- Zebrafish International Resource Center

## Invertebrate

- 
- 
- Bloomington *Drosophila* Stock Center
  - National Resource for *Aplysia*
  - Resource Center for *Tetrahymena*

# Gabriella Miller Kids First Pediatric Research Program (Kids First)

- P40 supported facilities – resources for animal models
- Several P40 Centers provide expertise and services to the community
- P40 Centers will be happy to acquire and re-distribute models created by Kids First
- P40 FOA – create your own resource

# Summary

*ORIP supports development, enhancement and distribution of animal models of interest to multiple NIH ICs*

## Scientific Contacts:

- **R21 (PAR-19-369): Development of Animal Models and Related Biological Materials**
  - **Sige Zou, PhD; Telephone: 301-435-0749; Email: [sige.zou@nih.gov](mailto:sige.zou@nih.gov)**
- **R24 (RFA-OD-19-027): Resource-Related Research Projects for Development of Animal Models and Related Materials**
  - **Stephanie Murphy, VMD, PhD; Telephone: 301-451-7818; Email: [stephanie.murphy@nih.gov](mailto:stephanie.murphy@nih.gov)**
  - **Sige Zou, PhD; Telephone: 301-435-0749; Email: [sige.zou@nih.gov](mailto:sige.zou@nih.gov)**
- **P40 (PAR-17-006): Animal and Biological Material Resource Centers**
  - **Oleg Mirochnitchenko, PhD; Telephone: 301-435-0748; Email: [oleg.mirochnitchenko@nih.gov](mailto:oleg.mirochnitchenko@nih.gov)**

## Questions?

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# NIDCR Funding Opportunities

Emir Khatipov, Ph.D., Director,  
Bioinformatics, Computational Biology  
and Data Sciences Program  
Translational Genomics Research Branch,  
National Institute for Dental and Craniofacial Research

*November 21, 2019*



National Institute of Dental  
and Craniofacial Research



# NIDCR Program Announcements (PARs)

## Data Analysis

| FOA        | Title   | Scope   | Open date |
|------------|---|---|-----------|
| PAR-20-045 | <p>NIDCR Research Grants for Analyses of Existing Genomics Data</p> <p>(R01 Clinical Trial Not Allowed)</p>       | <ol style="list-style-type: none"> <li>1) Research addressing questions relevant to human dental, oral, or craniofacial (DOC) conditions or traits through analysis of existing and publicly available genomics data using statistical and computational approaches.</li> <li>2) Data analysis for each project using existing and/or novel methods to be developed in the same project, including machine learning-based methods (ML).</li> <li>3) Experimental or <i>in silico</i> work is required to validate data analysis results, or to validate a newly developed analytic method.</li> </ol> | 1/05/2020 |
| PAR-20-046 | <p>NIDCR Small Research Grants for Analyses of Existing Genomics Data</p> <p>(R03 Clinical Trial Not Allowed)</p> | <ol style="list-style-type: none"> <li>1) Same as above</li> <li>2) Same as above</li> <li>3) Experimental validation of data analysis results or new methods may be proposed, but the focus of the project should be on analysis of existing data.</li> </ol>  | 1/16/2020 |

# NIDCR Notice of Special Interest (NOSI)

FOA

Title

Scope

Mechanism

**NOT-DE-19-016**

Application  
period:  
January 7, 2020  
through  
January 8th, 2022

Notice of Special Interest (NOSI) of NIDCR in Supporting Discovery, Characterization, and Mechanistic Study of Genetic Variants Underlying Dental, Oral, and Craniofacial Diseases and Conditions.

Projects targeting human DOC phenotypes that propose specific aims in each of the following categories:

- 1) discovery of candidate causal genetic variants,
- 2) functional characterization of identified variants, and
- 3) mechanistic studies.

**R01:**

parent FOA  
PA-19-056,


Indicate this NOSI  
in the application

# NIDCR Program Announcements (PARs)

## (partnering with NICHD and NIEHS)

| FOA        | Title  | Scope   | Open date |
|------------|--|---|-----------|
| PAR-19-292 | Mechanistic Studies of Gene-Environment Interplay in Dental, Oral, Craniofacial, and Other Diseases and Conditions<br><br>( <b>R01</b> Clinical Trial Not Allowed)   | Applications that use animal models, in vitro systems, or ex vivo approaches to conduct mechanistic investigation of the interplay of genes/gene networks and environmental factors in dental, oral, craniofacial (DOC), and other diseases and conditions. | 9/05/2019 |
| PAR-19-293 | Development of Novel and Robust Systems for Mechanistic Studies of Gene-Environment Interplay in Dental, Oral, Craniofacial, and Other Diseases and Conditions<br><br>( <b>R21</b> Clinical Trial Not Allowed) | To develop novel and robust experimental systems that offer approaches complementary to human epidemiologic or in vivo studies to facilitate mechanistic investigation of gene-environment interplay in DOC and other diseases and conditions               | 9/16/2019 |

# Q & A

- To ask public questions, use the **Q&A** bar (right side of your screen).
- You can also use the “chat”  service to send private messages to the host or presenters throughout the webinar.



# FOAs for Data Analyses

- “Kids First R03-PAR”: <https://grants.nih.gov/grants/guide/pa-files/PAR-19-375.html>
- NIH “Parent” R03: <https://grants.nih.gov/grants/guide/pa-files/PA-19-052.html>
- NIH “Parent” R01: <https://grants.nih.gov/grants/guide/pa-files/PA-19-056.html>
- NCI: *Secondary Analysis and Integration of Existing Data to Elucidate the Genetic Architecture of Cancer Risk and Related Outcomes* (Contact: Melissa Rotunno, Ph.D [rotunnom@mail.nih.gov](mailto:rotunnom@mail.nih.gov))
  - R01: <https://grants.nih.gov/grants/guide/pa-files/PA-17-239.html>
  - R21: <https://grants.nih.gov/grants/guide/pa-files/PA-17-243.html>
- NIDCR: *Notice of Special Interest (NOSI) of NIDCR in Supporting Discovery, Characterization, and Mechanistic Study of Genetic Variants Underlying Dental, Oral, and Craniofacial Diseases and Conditions* <https://grants.nih.gov/grants/guide/notice-files/NOT-DE-19-016.html>
- *NIDCR Research Grants for Analyses of Existing Genomics Data (R01)* <https://grants.nih.gov/grants/guide/pa-files/PAR-19-390.html>
- *NIDCR Small Research Grants for Analyses of Existing Genomics Data (R03)* <https://grants.nih.gov/grants/guide/pa-files/PAR-20-046.html>



# FOAs for Variant Validation

- **ORIP: *Development of Animal Models and Related Biological Materials for Research (R21 Clinical Trial Not Allowed)***  
<https://grants.nih.gov/grants/guide/pa-files/PAR-19-369.html>
- **ORIP: *Resource-Related Research Projects for Development of Animal Models and Related Materials (R24 Clinical Trials Not-Allowed)***  
<https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-19-027.html>
- **NIDCR: *Mechanistic Studies of Gene-Environment Interplay in Dental, Oral, Craniofacial, and Other Diseases and Conditions (R01 Clinical Trial Not Allowed)***. <https://grants.nih.gov/grants/guide/pa-files/PAR-19-292.html>
- **NIDCR: *Development of Novel and Robust Systems for Mechanistic Studies of Gene-Environment Interplay in Dental, Oral, Craniofacial, and Other Diseases and Conditions (R21 Clinical Trial Not Allowed)***.  
<https://grants.nih.gov/grants/guide/pa-files/PAR-19-293.html>
- **NHGRI: *Novel Approaches for Relating Genetic Variation to Function and Disease (R01 Clinical Trial Not Allowed)***  
<https://grants.nih.gov/grants/guide/pa-files/pa-18-868.html>
- To pursue collaborations with the [Knockout Mouse Phenotyping Program \(KOMP2\)](#), contact: [KidsFirstKOMP@nih.gov](mailto:KidsFirstKOMP@nih.gov)



# Thank You!

**To receive updates about future Kids First opportunities,  
sign up for the listserv:**

<https://list.nih.gov/cgi-bin/wa.exe?SUBED1=KIDSFIRST&A=1>





# X01 Helpful Links

- <https://grants.nih.gov/grants/guide/pa-files/PAR-19-390.html>
- <https://commonfund.nih.gov/kidsfirst/faq>
- <https://kidsfirstdrc.org/>
- <https://portal.kidsfirstdrc.org>
- <https://osp.od.nih.gov/scientific-sharing/institutional-certifications/>



# Examples of Research Project Grants (R21)



Image-guided robot for high-throughput microinjection of *Drosophila* embryos:

- Develop a computer vision guided robotic microinjector for high-throughput microinjection



Enhancing CRISPR-Cas for disease modeling in *Xenopus*:

- Examine a CRISPR technique for its efficiency in generating mutations in *Xenopus*



Genetic Modification to Harness the Regenerative Power of the African Spiny Mouse:

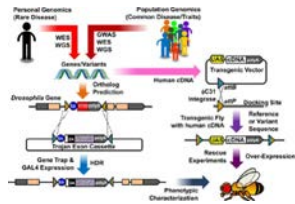
- Develop a gene knockout technique in *Acomys*



Germ cell preservation of immunodeficient pigs utilizing embryo complementation approach:

- Developing a standardized procedure to preserve germ cells from any type of immunodeficient pigs

# Examples of Resource-Related Research Projects Grants (R24)



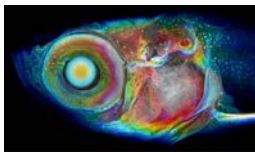
## A Comprehensive Human cDNA Library For Functional Gene Replacement in *Drosophila*:

- Generate human cDNA library and related transgenic flies to facilitate clinical genomics interpretation



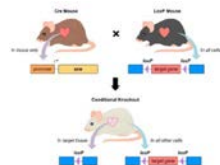
## Research Resources for Model Amphibians:

- Develop genomic and bioinformatic resources for the Mexican axolotl (*Ambystoma mexicanum*)



## Groundwork for a Synchrotron MicroCT Imaging Resource for Biology:

- Enable high-throughput, quantitative, 3D histological phenotyping of whole, millimeter-scale animals



## CRE Driver Strain Resources:

- A comprehensive set of well-characterized Cre Driver mouse lines and related information resources

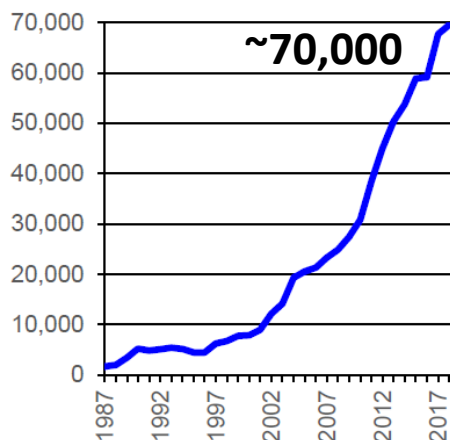
# Bloomington *Drosophila* Stock Center (P40 OD018537)

## Kevin R. Cook, Indiana University, IN

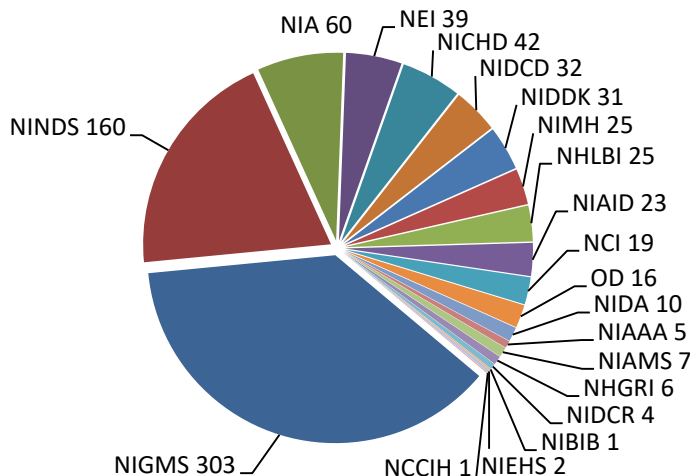
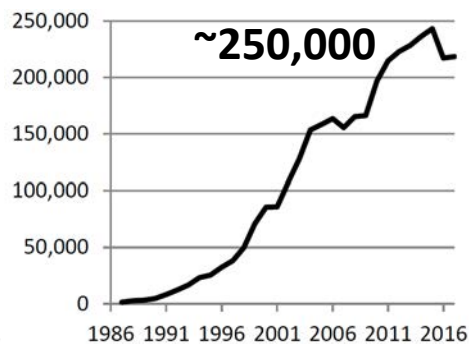
Funded by: ORIP (Primary), NIGMS, NICHD, NINDS, HHMI

The Center collects, maintains and distributes genetically defined strains of *Drosophila* with significant research value

### Stocks in Collection

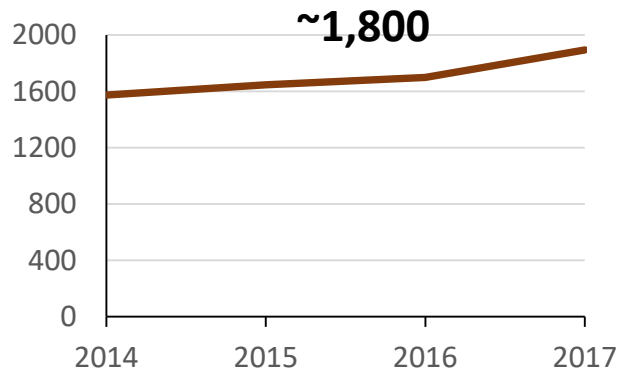


### Samples Shipped Annually



Support  
>1,000  
NIH grants

### Publications Citing BDSC Annually



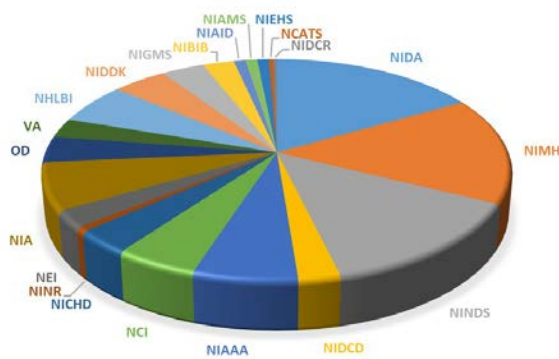
# Rat Resource and Research Center (RRRC, P40 OD011062)

## Elizabeth Bryda, University of Missouri

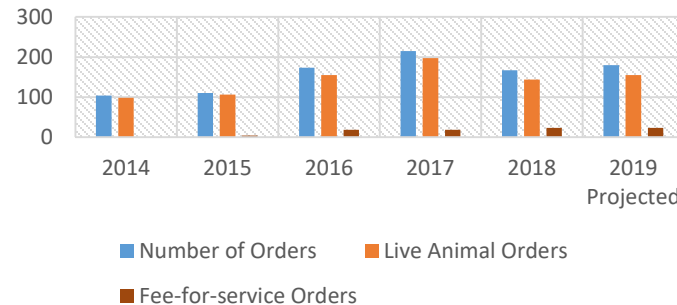
Current holdings: >450 unique rat strains/stocks and 6 embryonic stem cell lines

The RRRC provides a unique repository service to the biomedical community for importing, storing and distributing valuable rat strains and providing rat-related services

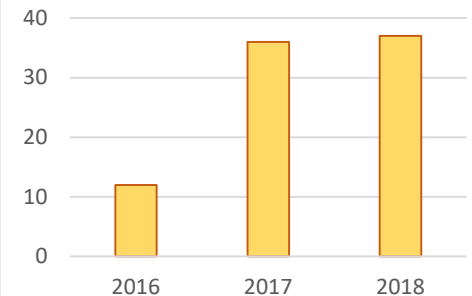
RRRC USERS' NIH FUNDING SOURCES 2014-2019



RRRC Orders



Publications By RRRC Users



Additional services: unique cryopreservation approaches (ICSI), genotyping/genetic characterization, rederivation, genome editing (CRISPR/Cas9) for model creation, tissue/sample isolation, phenotyping, colony management, microbiota characterization

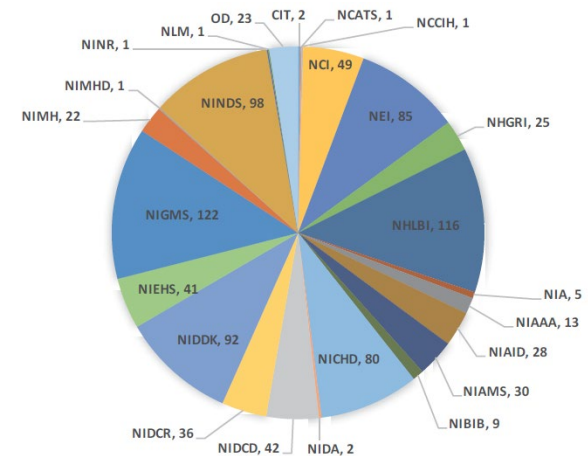
# Zebrafish International Resource Center (P40 OD011021)

## Monte Westerfield, University of Oregon, OR

The Zebrafish International Resource Center is a zebrafish repository that provides animals, materials and services to the research community for more than 20 years

Funded by ORIP and NICHD

- The only national repository for zebrafish genetic stocks (>11,600 lines and 39,000 alleles) and research materials (antibodies, cDNA/EST, etc.)
- Provides the highest quality animal lines raised under stringent health monitoring
- Develops, characterizes, maintains, cryopreserves and distributes both wild-type strains and mutant zebrafish
- Provides pathology and consultation services
- Develops diagnostic platforms to screen for common pathogens that are threats to laboratory zebrafish



Resources and services to PIs supported by 23 NIH Institutes

Last year, ZIRC distributed 114,555 animals to 530 laboratories (94% NIH supported)